Individual Safety Report

3215423-6-06-01

For use by user-facilities, butors and manufacturers for MANDATORY reporting

Approved by FDA on 10/29/93

Mfr report # 970709-107012240

UF/Dist report #

FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] In confidence	53 Year(s) or Date of birth: [redacted]	☐ female ☒ male	250 lbs or kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

- ☐ death (mo/day/yr)
- ☐ life-threatening
- ☒ hospitalization - initial or prolonged
- ☒ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event (mo/day/yr): 06/27/95

4. Date of this report (mo/day/yr): 03/08/99

5. Describe event or problem

A report from an attorney of a male patient who was hospitalized in JUN-95 with a diagnosis of acute renal failure, acute hepatitis, thrombocytopenia and coagulopathy secondary to liver disease while taking TYLENOL with codeine #3 (acetaminophen with codeine). The patient was discharged on 14-JUL-95.

Follow-up information received 22-Feb-99: Medical records indicate a 53-year-old man, with a history of hypertension, atherosclerotic coronary disease, chronic obstructive pulmonary disease, chronic back pain due to a traumatic lumbar vertebra fracture (1993) and chronic alcohol abuse (3-4 six-packs every Friday and 1-6 beers on any given night of the week) was hospitalized on 27-Jun-95 with shortness of breath, nausea, vomiting (vomitus black), diarrhea, black stool, and hypotension. Symptoms started 2 days prior to admission with malaise, generalized weakness, cramping, periumbilical pain followed by nausea and vomiting. During hospitalization from 27-Jun-95 to 14-Jul-95, alcoholic hepatitis, alcoholic dependency continuous, septicemia, alcoholic gastritis with hemorrhage, acute renal failure, defibrination syndrome, hepatitis, chronic blood loss anemia, hyperosmolality, hypopotassemia, ascites, complications from gastric device, paralytic ileus and pulmonary collapse were diagnosed. Medications prior to admission included for treatment of back pain: TYLENOL with codeine #3 3

(Cont.)

6. Relevant tests/laboratory data, including dates

None provided

Follow-up information received 22-Feb-99:
hemoglobin 27-Jun 16.4/13.6, 29-Jun 11.9, 11-Jul 8.6
creatinine 27-Jun 4.3, 01-Jul 5.1, 12-Jul 1.8
LDH 27-Jun 5681, 28-Jun 7865, 29-Jun 4883, 02-Jul [illegible], 12 Jul 268
AST 27-Jun 6325, 28-Jun 7052, 29-Jun 5176, 02-Jul 220, 12-Jul 23
ALT 27-Jun 688, 28-Jun 964, 29-Jun 609, 02-Jul 179, 12-Jul 36

(Cont.)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Unspecified alcohol intake

Follow-up information received 22-Feb-99: hypertension, atherosclerotic coronary disease, chronic obstructive pulmonary disease, chronic back pain due to a traumatic lumbar vertebra fracture (1993) and chronic alcohol abuse (3-4 six-packs every Friday and 1-6 beers on any given night of the week). The patient did note, "the abdominal girth has been increasing over the last several weeks".

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 TYLENOL WITH CODEINE #3 TABLETS (ACETAMINOPHEN & CODEINE)

#2 LORTAB (ACETAMINOPHEN W/HYDROCODONE BITARTRATE)

2. Dose, frequency & route used

#1 3 TAB, qd, ORAL

#2 2 TAB, qd, ORAL

3. Therapy dates (if unknown, give duration) (from/to (or best estimate))

#1 Unknown

#2 Unknown

4. Diagnosis for use (indication)

#1 back pain

#2 back pain

5. Event abated after use stopped or dose reduced

#1 ☐ yes ☒ no ☐ doesn't apply

#2 ☐ yes ☒ no ☐ doesn't apply

6. Lot # (if known)

#1 UNK

#2 UNK

7. Exp. date (if known)

#1 UNK

#2 UNK

8. Event reappeared after reintroduction

#1 ☐ yes ☐ no ☒ doesn't apply

#2 ☐ yes ☐ no ☒ doesn't apply

9. NDC # - for product problems only (if known)

NA

10. Concomitant medical products and therapy dates (exclude treatment of event)

1) CALAN (VERAPAMIL HYDROCHLORIDE) Unknown
2) HYTRIN (TERAZOSIN HYDROCHLORIDE) Unknown

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

R. W. JOHNSON PHARM. RESEARCH INSTITUTE
DIV. OF ORTHO PHARMACEUTICAL CORPORATION
ROUTE 202, P.O. BOX 3[illegible]
RARITAN NJ 08869-06[illegible]

(Informing unit)

DSS

MAR 10 1999

ADVERSE EVENT REPORTING SYSTEM

2. Phone number: (908) 704-4600

3. Report source (check all that apply)

- ☐ foreign
- ☐ study
- ☐ literature
- ☒ consumer
- ☐ health professional
- ☐ user facility
- ☐ company representative
- ☐ distributor
- ☐ other:

4. Date received by manufacturer (mo/day/yr): 02/23/99

5. (A) NDA # 85-055
IND #
PLA #
pre-1938 ☐ yes
OTC product ☐ yes

6. If IND, protocol #

7. Type of report (check all that apply)

- ☐ 5-day ☒ 15-day
- ☐ 10-day ☐ periodic
- ☐ Initial ☒ follow-up # 1

8. Adverse event term(s)

1) RENAL FAILURE ACUTE
2) HEPATITIS
3) THROMBOCYTOPENIA
4) COAGULATION DISORDER
5) HEPATOCELLULAR DAMAGE
6) DRUG DEPENDENCE
7) SEPSIS

(Cont.)

9. Mfr. report number: 970709-107012240

E. Initial reporter

1. Name, address & phone #

CONSUMER, ESQ
[redacted]

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MAR 09 1999

BY: _____

2. Health professional? ☐ yes ☒ no

3. Occupation: Attorney

4. Initial reporter also sent report to FDA ☐ yes ☐ no ☒ unk

Form 3500A Facsimile

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Individual Safety Report

3215423-6-00-02*

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For use by user-facilities, istributors and manufacturers for **MANDATORY** reporting

Approved by FDA on 10/29/93

MFR report # 970709-107012240

UF/Distr report #

FDA Use Only

A. Patient information

1. Patient identifier: In confidence
2. Age at time of event: or Date of birth:
3. Sex: ☐ female ☐ male
4. Weight: ____ lbs or ____ kgs

B. Adverse event or product problem

1. ☐ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
   - ☐ death ____ (mo/day/yr)
   - ☐ life-threatening
   - ☐ hospitalization - initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other:

3. Date of event (mo/day/yr)

4. Date of this report (mo/day/yr)

5. Describe event or problem

DSS

MAR 1 0 1999

ADVERSE EVENT REPORTING SYSTEM

6. Relevant tests/laboratory data, including dates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

RECEIVED

MAR 0 9 1999

BY: _____

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #3 ACETYLSALICYLIC ACID
   #4

2. Dose, frequency & route used
   #3 Unknown, PRN, ORAL
   #4

3. Therapy dates (if unknown, give duration) (mo/da/yr (or best estimate))
   #3 Unknown
   #4

4. Diagnosis for use (indication)
   #3 back pain
   #4

5. Event abated after use stopped or dose reduced
   #3 ☐ yes ☒ no ☐ doesn't apply
   #4 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
   #3 UNK
   #4

7. Exp. date (if known)
   #3 UNK
   #4

8. Event reappeared after reintroduction
   #3 ☐ yes ☐ no ☒ doesn't apply
   #4 ☐ yes ☐ no ☐ doesn't apply

9. NDC # - for product problems only (if known)
   NA

10. Concomitant medical products and therapy dates (exclude treatment of event)

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)
   R. W. JOHNSON PHARM. RESEARCH INSTITUTE
   DIV. OF ORTHO PHARMACEUTICAL CORPORATION
   ROUTE 202, P.O. BOX 300
   RARITAN NJ 08869-0602

   (Informing unit)

2. Phone number
   (908) 704-4600

3. Report source (check all that apply)
   - ☐ foreign
   - ☐ study
   - ☐ literature
   - ☐ consumer
   - ☐ health professional
   - ☐ user facility
   - ☐ company representative
   - ☐ distributor
   - ☐ other:

4. Date received by manufacturer (mo/day/yr)

5. (A) NDA # ____
   IND # ____
   PLA # ____
   pre-1938 ☐ yes
   OTC product ☐ yes

6. If IND, protocol #

7. Type of report (check all that apply)
   - ☐ 5-day ☐ 15-day
   - ☐ 10-day ☐ periodic
   - ☐ Initial ☐ follow-up # ____

8. Adverse event term(s)

9. Mfr. report number

E. Initial reporter

1. Name, address & phone #

2. Health professional? ☐ yes ☐ no

3. Occupation

4. Initial reporter also sent report to FDA ☐ yes ☐ no ☐ unk

Form 3500A Facsimile

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

Continuation Sheet for FDA-3500A Form

Mfr. report # : 970709-107012240

B.5 Describe event or problem (Cont...)

tablets/day, Lortab (acetaminophen with hydrocodone bitartrate) 2 tablets/day, acetylsalicylic acid intermittently; for treatment of hypertension: Calan (verapamil hydrochloride), Hytrin (terazosin hydrochloride). The treating physicians considered septicemia as spontaneous bacterial peritoritis as well as diverticulitis with resultant diarrhea; hepatitis as alcohol hepatitis plus effect of acetaminophen; acute renal failure due to acetaminophen or acute glomerulonephritis or from vomiting and diarrhea; thrombocytopenia and coagulopathy secondary to liver disease; GI bleeding due to alcoholic gastritis, thrombocytopenia, systemic inflammatory response syndrome. Patient was discharged from hospital on 14-Jul-95, still on medications (not specified), activity allowed as tolerated.

B.6 Relevant tests/laboratory data, including dates (Cont...)

bilirubin 27-Jun 1.2, 29-Jun 2.5, 02-Jul 3.7
protein 12-Jul 7.0
triglyceride 27-Jun 1154, 28-Jun 699, 12-Jul 148
PTT 27-Jun 85.2, 29-Jun 45.6, 03-Jul 22.1
WBC 27-Jun 20,000, 28-Jun 10,600
platelets 27-Jun 29,000, 02-Jul 77,000, 10-Jul 157,000
hepatitis screen A/B/C negative
27-Jun acetaminophen level < 5 mcg/mL

G. All manufacturers (Cont...)

G.8 Adverse event term(s)

8)GI HAEMORRHAGE
9)ANAEMIA
10)ELECTROLYTE ABNORMALITY
11)HYPOKALAEMIA
12)ASCITES
13)ADE, NOS
14)ILEUS PARALYTIC
15)PULMONARY COLLAPSE
16)HYPOTENSION

DSS
MAR 10 1999
ADVERSE EVENT REPORTING SYSTEM

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MAR 09 1999
BY: